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**Europäisches
Patentamt**

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Recherchen-
abteilung

**European
Patent Office**

Branch at
The Hague
Search
division

**Office européen
des brevets**

Département à
La Haye
Division de la
recherche

De Clercq, Ann
De Clercq, Brants & Partners cv.,
Edgard Gevaertdreef 10a
9830 Sint-Martens-Latem
BELGIQUE

Datum/Date

31.10.2001

Zeichen/Ref./Réf. UCL-021-EP	Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./Brevet n°. 01870030.2
Anmelder/Applicant/Demandeur/Patentinhaber/Proprietor/Titulaire UNIVERSITE CATHOLIQUE DE LOUVAIN	

COMMUNICATION

The European Patent Office herewith transmits

- the European search report
- the declaration under Rule 45 EPC
- the partial European search report under Rule 45 EPC
- the supplementary European search report concerning the international application under Article 157(2) EPC relating to the above-mentioned European patent application. *Copies of the documents cited in the search report are enclosed.*

The following specifications given by the applicant have been approved by the Search Division :

- Abstract Title Figure
- The abstract was modified by the Search Division and the definitive text is attached to this communication.
- The following figure will be published with the abstract, since the Search Division considers that it better characterises the invention than the one indicated by the applicant.

Figure:

- Additional copy(copies) of the documents cited in the European search report.

C. Humbert
C. Humbert



REFUND OF THE SEARCH FEE

If applicable under Article 10 Rules relating to fees, a separate communication from the Receiving Section on the refund of the search fee will be sent later.



CLAIMS INCURRING FEES

The present European patent application comprised at the time of filing more than ten claims.

Only part of the claims have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims and for those claims for which claims fees have been paid, namely claim(s):

No claims fees have been paid within the prescribed time limit. The present European search report has been drawn up for the first ten claims.

LACK OF UNITY OF INVENTION

The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

see sheet B

All further search fees have been paid within the fixed time limit. The present European search report has been drawn up for all claims.

As all searchable claims could be searched without effort justifying an additional fee, the Search Division did not invite payment of any additional fee.

Only part of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the inventions in respect of which search fees have been paid, namely claims:

None of the further search fees have been paid within the fixed time limit. The present European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims, namely claims:

1-10 (partially)



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-10 (partially)

Invention 1:

Methods for detecting and/or identifying (differential detection) non-tuberculosis Mycobacterium using an isolated nucleic acid derived from the p34 upstream gene region represented by SEQ ID NO:57, its complement, or portions thereof, or probes specifically hybridising to this sequence, or the corresponding sequence wherein T has been replaced by U, or species-specific primer pairs comprising said sequence.

2. Claims: 1-10 (partially)

Invention 2 to 68:

Methods for detecting and/or identifying (differential detection) non-tuberculosis Mycobacterium using an isolated nucleic acid derived from the p34 upstream gene region represented by SEQ ID NO:59, its complement, or portions thereof, or probes specifically hybridising to this sequence, or the corresponding sequence wherein T has been replaced by U, or species-specific primer pairs comprising said sequence.

Idem for invention 3 to 68 but limited to the sequences having SEQ ID NOS 60-64,67,69-74,8-54, and 1-7. (SEQ ID NO:60 represents invention number 3,... ,SEQ ID NO:62 represents invention number 5,... , and SEQ ID NO:7 represents invention number 68)



DOCUMENTS CONSIDERED TO BE RELEVANT									
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.)						
X	<p>COETSIER CHRISTOPHE ET AL: "Duplex PCR for differential identification of <i>Mycobacterium bovis</i>, <i>M. avium</i>, and <i>M. avium</i> subsp. <i>paratuberculosis</i> in formalin-fixed paraffin-embedded tissues from cattle."</p> <p>JOURNAL OF CLINICAL MICROBIOLOGY, vol. 38, no. 8, August 2000 (2000-08), pages 3048-3054, XP002172497</p> <p>ISSN: 0095-1137</p> <p>* page 3051 - page 3053; figures 1,2; tables 1,2 *</p> <p>---</p>	1-10	C12Q1/68						
X	<p>VANNUFFEL P ET AL: "P34 and F57 based-multiplex PCR assay for discrimination between tuberculous and nontuberculous mycobacteria."</p> <p>ABSTRACTS OF THE INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND, vol. 38, 1998, page 158 XP001010524</p> <p>38th Interscience Conference on Antimicrobial Agents and Chemotherapy; San Diego, California, USA; September 24-27, 1998, 1998</p> <p>* the whole document *</p> <p>-----</p>	1-10	<p>-----</p> <p>-----</p> <p>-----</p> <p>-----</p>						
The present search report has been drawn up for all claims			TECHNICAL FIELDS SEARCHED (Int.Cl.7)						
3	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Place of search</td><td style="width: 33%;">Date of completion of the search</td><td style="width: 34%;">Examiner</td></tr> <tr> <td>THE HAGUE</td><td>23 July 2001</td><td>Gabriels, J</td></tr> </table>	Place of search	Date of completion of the search	Examiner	THE HAGUE	23 July 2001	Gabriels, J		C12Q
Place of search	Date of completion of the search	Examiner							
THE HAGUE	23 July 2001	Gabriels, J							
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>									



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- RECEIVED -

10 AUG. 2001

RECOMMANDÉ
AANGEKEURD

Datum/Date
08.08.01

Zeichen/Ref./Réf.

UCL-021-EP

Anmeldung Nr./Application No./Demande n°./Patent Nr./Patent No./Brevet n°

01870030.2-2116/

Anmelder/Applicant/Demandeur//Patentinhaber/Proprietor/Titulaire
UNIVERSITE CATHOLIQUE DE LOUVAIN

COMMUNICATION

The European Patent Office herewith transmits the partial European search report under Rule 46(1) EPC relating to the above-mentioned European patent application.

Copies of the documents cited in the search report are enclosed.

The applicant's attention is drawn to the following:

The search Division informs the applicant that if the European search report is also to cover inventions other than the invention first mentioned in the claims, a further search fee must be paid for each of these inventions, within ONE MONTH after notification of this communication.

If the application has been filed up to 30 June 1999, the search fee in force before 01 July 1999 (EUR 869,--) or the equivalent applicable on the date of payment is payable.

This applies also to the search fees requested under Rule 46(1) EPC.

See also OJ EPO 06/1999, 405.

The abstract was modified by the Search Division and the definitive text is attached to the present communication.

Additional set(s) of copies of the documents cited in the European search report is (are) enclosed as well.



Note to users of the automatic debiting procedure:

Unless the EPO receives prior instructions to the contrary, the search fee(s) will be debited on the last day of the period for payment. For further details see the Arrangements for the automatic debiting procedure, Supplement to OJ EPO 02/1999.

REGISTERED LETTER



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT
under Rule 46, paragraph 1 of the European Patent Convention

Application Number

EP 01 87 0030

DOCUMENTS CONSIDERED TO BE RELEVANT			
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
X	<p>COETSIER CHRISTOPHE ET AL: "Duplex PCR for differential identification of <i>Mycobacterium bovis</i>, <i>M. avium</i>, and <i>M. avium</i> subsp. <i>paratuberculosis</i> in formalin-fixed paraffin-embedded tissues from cattle."</p> <p>JOURNAL OF CLINICAL MICROBIOLOGY, vol. 38, no. 8, August 2000 (2000-08), pages 3048-3054, XP002172497</p> <p>ISSN: 0095-1137</p> <p>* page 3051 - page 3053; figures 1,2; tables 1,2 *</p> <p>---</p> <p>-/-</p>	1-10	C12Q1/68
LACK OF UNITY OF INVENTION			
<p>The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:</p> <p>see sheet B</p> <p>The present partial European search report has been drawn up for those parts of the European patent application which relate to the invention first mentioned in the claims.</p>			
3	Place of search	Date of completion of the search	Examiner
EPO FORM 1503.03.82 (P04C27)	THE HAGUE	23 July 2001	Gabriels, J
CATEGORY OF CITED DOCUMENTS		<p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date D : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>	
<p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p>			



European Patent
Office

PARTIAL EUROPEAN SEARCH REPORT

Application Number
EP 01 87 0030

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.Cl.7)
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	TECHNICAL FIELDS SEARCHED (Int.Cl.7)
X	VANNUFFEL P ET AL: "P34 and F57 based-multiplex PCR assay for discrimination between tuberculous and nontuberculous mycobacteria." ABSTRACTS OF THE INTERSCIENCE CONFERENCE ON ANTIMICROBIAL AGENTS AND, vol. 38, 1998, page 158 XP001010524 38th Interscience Conference on Antimicrobial Agents and Chemotherapy; San Diego, California, USA; September 24-27, 1998, 1998 * the whole document * -----	1-10	



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

1. Claims: 1-10 (partially)

Invention 1:

Methods for detecting and/or identifying (differential detection) non-tuberculosis Mycobacterium using an isolated nucleic acid derived from the p34 upstream gene region represented by SEQ ID NO:57, its complement, or portions thereof, or probes specifically hybridising to this sequence, or the corresponding sequence wherein T has been replaced by U, or species-specific primer pairs comprising said sequence.

2. Claims: 1-10 (partially)

Invention 2 to 68:

Methods for detecting and/or identifying (differential detection) non-tuberculosis Mycobacterium using an isolated nucleic acid derived from the p34 upstream gene region represented by SEQ ID NO:59, its complement, or portions thereof, or probes specifically hybridising to this sequence, or the corresponding sequence wherein T has been replaced by U, or species-specific primer pairs comprising said sequence.

Idem for invention 3 to 68 but limited to the sequences having SEQ ID NOS 60-64,67,69-74,8-54, and 1-7. (SEQ ID NO:60 represents invention number 3,... ,SEQ ID NO:62 represents invention number 5,... , and SEQ ID NO:7 represents invention number 68)

The common concept shared by all the claims is the detection and/or identification (differential detection) of non-tuberculosis Mycobacterium strains using species-specific oligonucleotides derived from the upstream p34 gene region. Methods for the detection and/or identification (differential detection) of Mycobacterium strains using species-specific probes and/or primer pairs derived from the upstream p34 gene region are however known in the prior art: D1 (Coetsier C. et al.,2000), D2 (Vannuffel P. et al.,1998).

In view of this prior art (D1,D2), the remaining problem in the present application can thus be defined as the provision of alternative primers and probes derived from the upstream p34 gene region for the detection and/or identification (differential detection) of non-tuberculosis Mycobacterium. The solutions given are: SEQ ID NOS: 57,59-64,67,69-74,8-54, and 1-7.

Each individual sequence selected from SEQ ID NOS:



The Search Division considers that the present European patent application does not comply with the requirements of unity of invention and relates to several inventions or groups of inventions, namely:

57,59-64,67,69-74,8-54, and 1-7 represents an independent solution to the problem of the present application.

In view of the fact that methods for the differential detection of *Mycobacterium* strains using the upstream p34 gene region are already well known in the prior art, due to the essential differences in primary structure and species-specificity of the primers and probes described above, and due to the fact that no other technical features can be distinguished which, in the light of the prior art, could be regarded as "special technical features" common to the alternative solutions of the problem of this application, the ISA is of the opinion that there is no single inventive concept underlying the inventions of the present application in the sense of rule 13.1 PCT. Consequently, there is lack of unity and the different solutions given, e.g. SEQ ID NOS: 57,59-64,67,69-74,8-54, and 1-7, represent different inventions not belonging to a common inventive concept are formulated as the different subjects on the communication pursuant to Art.17(3)(a) PCT.

The ISA has searched the first invention listed above (claims 1-10 (partially))

The present European patent application comprised at the time of filing more than ten claims. No claims fees have been paid within the prescribed time limit.

The present communication therefore does not take into account any claims other than those mentioned hereabove.